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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,791	01/16/2004	Peter Osypka	SMB-PT090 (P 03 491 m US)	8144
3624	7590	06/01/2006	EXAMINER	
VOLPE AND KOENIG, P.C. UNITED PLAZA, SUITE 1600 30 SOUTH 17TH STREET PHILADELPHIA, PA 19103			MANUEL, GEORGE C	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,791	OSYPKA, PETER	
	Examiner	Art Unit	
	George Manuel	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/9/04, 1/16/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Preston '461 in view of Phillips, Jr. et al '135.

Preston discloses a bipolar electrode comprising a cathode that may be attached to the distal end of lead 30 and an anode that may be attached to lead 30 proximal where the pacemaker connects to the lead 30. Preston further teaches the anode may be in the superior vena cava.

One of ordinary skill in the art would have found it obvious to use the teaching of Preston with the pacemaker of Phillips, Jr. et al because the lead 10 shown in Phillips, Jr. et al is an equivalent lead to that disclosed in Preston.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Preston '461 in view of Phillips, Jr. et al '135 and further in view of Dutcher et al '090.

Preston in view of Phillips, Jr. et al meet all of the limitations of claim 5 except for the anode being perforated and arranged within a perforated silicon jacket.

Dutcher et al disclose an anode 328 and a mesh 313 and teach the lead body 314 comprises a biocompatible material, such as silicon rubber.

One of ordinary skill in the art would have found it obvious to use the teaching of Dutcher et al to form the anode of Preston in view of Phillips, Jr. et al as being perforated and arranged within a perforated silicon jacket because the teaching of Dutcher et al suggest using silicon as an insulator for an anode and using a mesh which has perforations to increase tissue contact.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Preston '461 in view of Phillips, Jr. et al '135 and further in view of Herscovici et al '418.

Preston in view of Phillips, Jr. et al meet all of the limitations of claims 7 and 8 except for two anodes and two cathodes and a fork for the supply lines.

Herscovici et al teach using a common carrier 14 and provide for two cathodes and two anodes. See Fig. 1.

One of ordinary skill in the art would have found it obvious to combine the lead combination of Herscovici et al with the device of Preston in view of Phillips, Jr. et al

because the lead arrangement of Herscovici et al is intended to be used with a pacemaker. Further, one of ordinary skill in the art would have found it obvious to provide a fork arrangement for the carrier 14 for ease of manufacture for connecting a multi-element lead to the pacemaker.

Response to Arguments

Applicant's arguments filed 3/13/06 have been fully considered but they are not persuasive. The location, an entrance into the vein, is a vague limitation clearly met by the location of the anode between 50 and 52 shown in Preston. For example, the left subclavian vein is an entrance into the vein.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art would have found it an obvious expedient to adapt the connector of Philips Jr. et al with the lead of Preston because most pacemaker leads need to be adapted to specific pacemaker connections and it is well settled that implantable pacemakers are tested externally before being implanted.

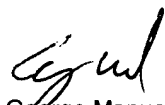
In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that

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any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.


George Manuel
Primary Examiner
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5/24/06